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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,186	11/04/2003	Joseph L. Duffy	21167	6239

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EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/701,186

Applicant(s)

DUFFY ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-9 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) 17, 18, 22 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 19 is/are allowed.
- 6) ☒ Claim(s) 6-9, 14, 15, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

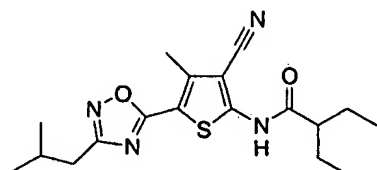
## DETAILED ACTION

Claims 6-9 and 14-23 are pending in the application.

### ***Election/Restrictions***

Applicants' election with traverse of Group I (claims 1-16), and the species of Example 1 (reproduced below) found at the bottom of page 28, in the reply filed on December 22, 2004 is acknowledged.

### EXAMPLE 1



The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Claims 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being

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drawn to a nonelected invention. Newly added claims 22 and 23 are also withdrawn since these claims are also directed to methods of use. Applicant timely traversed the restriction (election) requirement in the reply filed on December 10, 2004.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9, 14, 15, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 8, 9 and 20 are indefinite because claim 6 has the definitions for the  $R^4$  and  $R^5$  variables, which

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definitions are not needed in the instant amended claim. In claims 6 and 20, an "and" is needed after "Heteroaryl" under the definition of  $R^4$ . Claim 14 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and thereby establishing that no other subject matter is missing from the claim. In claim 20, the phrase "and when  $R^2$  is other than  $C_{1-10}$  alkyl,  $R^6$  is independently selected from the group" is unclear as to its meaning since the sentence is incomplete and  $R^2$  can only represent alkyl.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 21 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/706,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant products are generically described in the copending application. See in claim 14 of the copending application wherein  $R^1$  is alkyl;  $R^2$  is alkyl substituted with  $R^6$  (e.g., trifluoromethyl); and  $R^3$  is alkyl.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds

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derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating type 2 diabetes mellitus).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating type 2 diabetes mellitus. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicants' arguments filed July 1, 2005 have been fully considered. Applicants request that the obviousness-type double patenting be held in abeyance pending a determination that an allowable composition exists in the present application. Applicants argue that the motivation to "prepare products" in view of the co-pending application is not properly at issue since Applicants could combine the applications or abandon one or the other. Applicants further argue that the inquiry should focus on whether the claims of one application might unlawfully extend the monopoly on an obvious group of compounds claimed in a previous application if both applications, upon grant, would not expire at the same time.

In response, as stated above, the obviousness-type double patenting is a provisional since the conflicting claims have not been patented. Further, terminal disclaimers are filed for the purpose of preventing the



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prolongation of monopoly for patentably indistinct inventions and to enforce the covenant against dual ownership. See 37 CFR 1.321(c)(3) and terminal disclaimers in GATT effective date cases. Therefore, it is proper to make the rejection at this time and the rejection is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Cao et al. {US 2004/0122016}.

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Cao et al. disclose, for example, Compound I-A-2 on page 31 that is embraced by the instant claimed invention when R<sup>1</sup> is hydrogen, R<sup>2</sup> is heteroaryl (e.g., pyridyl) and R<sup>3</sup> is alkyl substituted with R<sup>6</sup> (e.g., phenylmethyl). Therefore, the instant claims are anticipated by Cao et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-9, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cao et al. {US 2004/0122016}, Hagen et al. {U.S. Pat. 5,422,335} and

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Kawai et al. {U.S. Pat. 6,048,880}, each taken alone or in combination with each other when similar utilities are asserted.

*Determination of the scope and content of the prior art (MPEP  
§2141.01)*

Applicants claim thiophene compounds. Cao et al. {paragraphs [0031]-[0048] on pages 5-6; paragraph [0064] on page 7; paragraph [0131] on page 24; paragraphs [0206]-[0222] on pages 115-118; and especially Compound I-A-2 on page 31)}, Hagan et al. {column 1, lines 5-51; column 2, lines 1-31; column 51, lines 31-41; column 52, lines 39-61; and especially the compounds Nos. 14.01, 14.04, 14.13, etc. in Table 14, columns 55-56} and Kawai et al. {columns 3-5; column 9, line 19; column 10, lines 60-61; column 15, lines 51-64; and column 16} each teach thiophene compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

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*Ascertainment of the difference between the prior art and the claims*  
*(MPEP §2141.02)*

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP*  
*§2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., inhibitors of protein kinases).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, asthma.

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Additionally, since Cao et al. and Kawai et al. each teach thiophene compounds, which are structurally similar to each other, and are useful in treating, for example, asthma, the combination of Cao et al. and Kawai et al. would also teach the instant claimed invention. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

### ***Response to Arguments***

Applicants' arguments filed July 1, 2005 have been fully considered. Applicants argue that the instant claimed invention is not obvious in view of Cao et al., Hagen et al. or Kawai et al., taken alone or in combination because the prior art references do not teach the activity of the compounds instant claimed, which is glucagon receptor antagonism.

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In response, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness.

In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir.

1990). Therefore, the rejection is deemed proper and therefore maintained.

#### ***Allowable Subject Matter***

Claims 16 and 19 are allowed over the art of record.

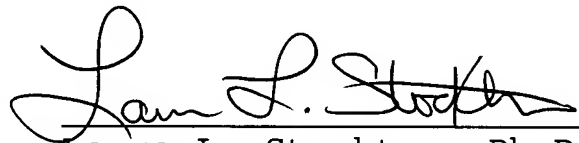
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information

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Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 8, 2005